EXHIBIT 6

From: Connelly, Beth
To: Landau, Dr. Craig; Baumgartner, Todd
CC: Rosen, Burt; Haddox, Dr. J. David; Coplan, Paul; Fanelli, Richard; Steiner, LaDonna
Sent: 10/19/2010 10:39:50 AM
Subject: REMS DOCKET SUBMISSION COMPLETED - TIME SENSITIVE REQUEST
Attachments: 2010-10-19 Purdue Endo Sandoz Comment Class-Wide Opioid REMS Docket FDA-2009-N-0143.pdf; 2790_001.pdf

All,
I have submitted the attached document to the Docket which has been assigned the "Comment tracking number: 80b7255f" [For reference, the confirmation sheet also attached]. In the confirmation sheet, it states that given certain regulations may have many comments, processing may take several weeks before it can be viewed on line.

If you have any questions, please let me know.
Regards,
Beth

Beth Connelly
Associate Director, Regulatory Affairs
Purdue Pharma L. P.
Telephone: [redacted]
email: [redacted]

From: Fanelli, Richard
Sent: Tuesday, October 19, 2010 5:53 AM
To: Landau, Dr. Craig; Baumgartner, Todd
Cc: Rosen, Burt; Haddox, Dr. J. David; Coplan, Paul; Connelly, Beth
Subject: Re: Fwd: REMS DOCKET SUBMISSION - TIME SENSITIVE REQUEST

Will do.

From: Landau, Dr. Craig
To: Baumgartner, Todd; Fanelli, Richard
Cc: Rosen, Burt; Haddox, Dr. J. David; Coplan, Paul
Sent: Tue Oct 19 01:58:06 2010
Subject: Fwd: REMS DOCKET SUBMISSION - TIME SENSITIVE REQUEST

Assuming it proofs well, let er' rip! Docket closes today! Thx Dave for the effort today.

Thanks,

Craig

Begin forwarded message:

From: "Haddox, Dr. J. David" [redacted]
Date: October 18, 2010 7:49:52 PM EDT
To: "Landau, Dr. Craig" [redacted], "Rosen, Burt" [redacted]
Cc: "Baumgartner, Todd" [redacted], "Fanelli, Richard" [redacted], "Connelly, Beth" [redacted], "Coplan, Paul" [redacted]
Subject: RE: REMS DOCKET SUBMISSION - TIME SENSITIVE REQUEST

All,

Attached is the submission, "signed" by PPLP, Endo, and Sandoz, in portable document format.

Dave

J. David Haddox, DDS, MD
VP, Health Policy
Purdue Pharma L.P.
One Stamford Forum
Stamford, CT 06901-3431
[redacted] ***W***
[redacted] ***F***

[redacted], ***Admin. Associate***
[redacted] ***W***

From: Landau, Dr. Craig
Sent: Monday, October 18, 2010 4:58 PM
To: Rosen, Burt
Cc: Baumgartner, Todd; Fanelli, Richard; Connelly, Beth; Coplan, Paul; Haddox, Dr. J. David
Subject: REMS DOCKET SUBMISSION - TIME SENSITIVE REQUEST
Importance: High

Burt,

Sandoz and Endo have agreed to sign on to our submission. I don't have a "word" version of the document to modify, so can you modify the text I highlighted in yellow to reflect the product mix of the three companies or delete the reference altogether if it doesn't fit as a document coming from these three companies. Once modified, can you send to Todd? Todd's group will make the actual "posting" tomorrow. We can then send to Sandoz (Laura Pethick) and Endo (Bob Barto).

Thanks-

Craig

Craig Landau, MD
Chief Medical Officer
VP Clinical, Medical and Regulatory Affairs
Purdue Pharma LLP
Stamford, CT 06901-3431
Cell [redacted]
Office [redacted]
Email [redacted]

Assistant
[redacted]

SUBMISSION TO FDA DOCKET NUMBER **FDA-2009-N-0143**

CLASS-WIDE OPIOID REMS

FDA should be complimented for the comprehensive manner in which they have approached their initiative to create a REMS for Certain Opioid Drugs ("The Opioid REMS"). We commend FDA for reaching out to a broad array of stakeholders, holding separate meetings with representatives of prescribers, dispensers, patient advocates, state regulators, manufacturers, distributors, vendors, and the public. FDA has also conducted Public and Advisory Committee Meetings to hear from the Industry Working Group and many other interested parties.

On July 22nd and 23rd FDA's Anesthetic & Life Support Drugs and Drug Safety & Risk Management Advisory Committees reviewed the FDA's REMS proposal for "extended-release and long-acting" opioid analgesic medications ("the long-acting opioid analgesics"). In the briefing material, FDA provided a detailed summary of the thorough review they gave to the input received from various interested parties, as well as the results of deliberations of FDA's own internal Working Groups. During the Advisory Committees' meeting, FDA presented its current thinking on what components should constitute The Opioid REMS. The members of the Advisory Committees rejected the FDA recommendations by a vote of 25-10.

It appeared that the Committees' votes were driven by two key areas of disagreement with FDA's proposal. The first was FDA's decision, against the recommendation of its internal Working Group on the Scope of The Opioid REMS, to define the class as only those long-acting opioid analgesics containing hydromorphone, oxycodone, oxymorphone, methadone, and morphine, as opposed to expanding the class to include the immediate-release, single-entity- and combination-opioid analgesic products containing every opioid analgesic drug substance. Committee members stated that these medications carry the same risks as the long-acting opioid analgesics. The Committee members expressed concern that misuse and abuse of the long-acting opioid analgesics would likely shift to the immediate-release opioid analgesic medicines and increase the already significant prevalence of nonmedical use of the immediate-

release opioid analgesic drug products. The concern expressed by the Committees' members was consistent with the recommendation of the FDA's internal Working Group on Scope, which concluded,

> "We ***recommend*** that the opioid REMS cover all opioid drugs, but be limited to requiring only prescriber education
>
> "The available data strongly suggest to us that a narrow REMS would be easily circumvented with potentially substantive consequences (under- and nontreatment, use of inappropriate substitutes posing safety problems). Thus, in proposing to broaden the scope of the REMS, we attempted to balance that with fewer requirements."

The second key area of disagreement between FDA and the Committees was the decision by FDA to recommend that prescriber training should be voluntary, as distinct from mandatory. Many members expressed their concerns that a voluntary training requirement would not be adequate and that many prescribers would simply not complete a training program. During the discussion, FDA put forward the idea that successful completion of training could be verified through linking evidence of completion to the DEA-registration process, using an existing database. Since all prescribers of controlled substances are required to be registered with DEA, and to renew their registration every three years, many of the Committee members felt it preferable to utilize an existing system for verification purposes, rather than requiring the creation of a new, redundant, system under which there would be no enforceable way of ensuring compliance.

CONCLUSION:

We would like to recommend that the appropriate response from FDA should be to require the implementation of their recommended REMS as presented to the July 22nd and 23rd Joint Advisory Committees' Meeting, as amended to include all single-entity- and combination-opioid analgesic drug products, consistent with the Advisory Committees' expressed concerns and the recommendation of the FDA Working Group

on Scope. It should be noted that two of the undersigned manufacturers market *both* long-acting and immediate-release opioid analgesic drug products.

Further, FDA should immediately implement the voluntary training as proposed, with a transition to a mandatory training or special certification requirement tied to DEA registration, once the DEA obtains authorization to utilize its registration process to require attestation of qualification by virtue of completion of such FDA-approved training or certification. FDA should support a policy to authorize a new DEA-registration requirement to prescribe or administer covered opioid analgesic drug products in Schedules IIN, IIIN, and any other schedules. FDA should also encourage the DEA and the Administration to support legislation to grant DEA the authorization to require attestation of prescriber compliance with such FDA-approved training or certification, as a condition of registration for the relevant scheduled drugs.

Purdue Pharma L.P., Endo Pharmaceuticals, Sandoz U.S.

Submit a Comment

Success! Your Comment Has Been Submitted

Comment Tracking Number: 80b7255f

Thank you for submitting a comment on the following NOTICES

Document ID: FDA-2009-N-0143-1061: Risk Evaluation and Mitigation Strategies for Certain Opioid Drugs; Notice of Public Meeting; Reopening of Comment Period

Your attached files:

2010-10-19 Purdue Endo Sandoz Comment Class-Wide Opioid REMS Docket FDA-2009-N-0143.pdf	✓ Successfully uploaded

When will I be able to view my comment online?

Your comment has been sent to the agency and will be available on Regulations.gov once it has been processed. Given certain regulations may have thousands of comments, processing may take several weeks before it can be viewed online. We value your comment, and encourage you to contact the agency directly for additional questions related to your specific comment.

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